REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated April 25, 2008 are respectfully requested.

I.   Status of the Claims

Claims 1-4, 28, and 29 are pending in the application.

No amendments to the claims are made herein.

II.   Rejections under 35 U.S.C. § 103

Claims 1-4 were rejected under 35 U.S.C. §103 as being obvious over WO 99/62496 to Ayer *et al.* in view of Jao *et al.* (U.S. Patent No. 5,252,338) and further in view of Eckenhoff *et al.* (U.S. Patent No. 4,717,566) and Theeuwes (U.S. Patent No. 4,111,202).

Claims 28-29 were rejected under 35 U.S.C. §103 as being obvious over WO 99/62496 to Ayer *et al.* in view of Jao *et al.* and further in view of Eckenhoff and Theeuwes and the Physician's Desk Reference.

These rejections are respectfully traversed for the following reasons.

A.   The Present Claims

The present claims, as exemplified by claim 1, relates to a dosage form comprising

(a)   a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semipermeable;

(b)   an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semipermeable portion of the membrane;

(c)   a delay layer located adjacent the exit orifice;

(d)   a drug layer located within the compartment between the delay layer and the expandable layer; and

(e)   *an interface boundary between the delay layer and the drug layer, the interface boundary being convex in shape relative to the exit orifice.*

The italicized language indicates an important feature of the claimed dosage form, which is nowhere described not suggested by any of the cited references, individually nor in combination.

B.   The Applied Art

The applied art is summarized in Applicants' Response of January 7, 008.

C.   Analysis

The pending claims relate to a dosage form having a delay layer and a drug layer, where the interface boundary between the delay layer and the drug layer is convex in shape relative to the exit orifice in the dosage form. The technological benefits of this feature are described at, *e.g.*, ¶¶ [00023] an [000124]-[000127] of the specification. This feature is neither taught nor suggested by the cited references, individually or in combination.

The outstanding obviousness rejections appear to be based on the reasoning that the description in Eckenhoff *et al.* and Theeuwes of a dosage form having certain components in a convex shape, in combination with the other cited references, renders obvious the claimed dosage form. However, Eckenhoff *et al.* and Theeuwes do not show or suggest a convex interface between a delay layer and a drug layer, as recited in the claims. The Examiner appears to use the isolated teachings of a *convex shape* in Eckenhoff *et al.* and Theeuwes, divorced from its context in the respective dosage forms, to correct the defect in the other cited references.

In Eckenhoff *et al.* a convex shaped object can be seen in some of the drawings. A reading of Eckenhoff *et al.* describes that any convex shaped object is not a delay layer, as claimed. Instead, the layers correspond to an expandable member or "push layer" of the dosage form (col. 9, line 48 - col. 10, line 18), and a dense member 20 that has a high specific gravity to prevent the passage of the dosage form from the rumen (*e.g.*, col. 12, lines 36-65). Neither the expandable member 18 nor the dense member 20 is equivalent to the delay layer and/or drug layer of the present claims.

Similarly, Theeuwes describes a convex film or membrane 18 that separates two compartments in a dosage form (*e.g.*, col. 5, lines 19-26). This film 18 is not equivalent to an interface boundary between a delay layer and a drug layer.

Applicants submit that the isolated teaching of a convex shape in a dosage form in no way renders obvious a convex-shaped interface boundary between a delay layer and a drug layer, as claimed, and which is no where taught or suggested by any of the cited references. This Examiner's reasoning in proffering the rejection overlooks the *claim element* (i.e., a convex shaped interface boundary between a delay layer and a drug layer) and focuses only on isolated claim *words* (i.e., "convex"). Such a rejection is scientifically unfounded and does not meet the standards for obviousness under 35 U.S.C. § 103. Using such reasoning, the Examiner may as well cite a magnifying glass or a egg to correct the defects in the primary references, as such objects include convex shapes and have as much to do with an interface boundary between a delay layer and a drug layer as the convex shapes of Eckenhoff *et al.* and Theeuwes.

With respect to the Examiner generic assertion that one cannot argue against an obviousness rejection by attacking the reference individually, Applicants note that U.S. patent law has never precluded an Applicant from pointing out defects in the Examiner's characterization of a reference or the reasoning behind a rejection. Nowhere in any Response in the present application have Applicants *attacked* Eckenhoff *et al.* and Theeuwes individually, which references are accepted for what they do, in fact, describe. Only the Examiner's characterization of these references and the logic behind the obviousness rejection are being questioned.

For at least the foregoing reasons, Applicants submit that the obviousness rejection is scientifically and legally flawed. Withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

IV.   Conclusion

In view of the foregoing, the claims pending in the application patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 590-0734.

Respectfully submitted,

Date:___July 25, 2008_____

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